

**Amendment and Response**

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Serial No.: 10/663,925

Confirmation No.: 2297

Filed: September 16, 2003

For: POLYMERS WITH SOFT SEGMENTS CONTAINING SILANE-CONTAINING GROUPS, MEDICAL DEVICES, AND METHODS

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**Remarks**

The Office Action mailed August 22, 2006 has been received and reviewed. Claims 1-11, 13-28, 30-34, and 39-40 are pending. Reconsideration and withdrawal of the rejections are respectfully requested.

**The 35 U.S.C. §102 Rejections**

The Examiner rejected claims 1-11 and 13-17 under 35 U.S.C. §102(b) as being anticipated by Gunatillake327 (WO 99/50327, U.S. 6,437,073). The Examiner rejected claims 1-11 and 13-17 under 35 U.S.C. §102(b) as being anticipated by Gunatillake863 (WO 99/03863, U.S. 6,420,452). These rejections are respectfully traversed.

Applicants' claims are directed to a segmented polymer that includes soft segments that are derived from the recited silane-containing compound, wherein each R<sup>3</sup> is independently an unsubstituted straight chain alkylene group that contains more than 4 carbons (e.g., claim 1).

In relation to segmented polymers, the terms "soft" and "hard" are widely known and used by those skilled in the art. The properties of such materials can be attributed to their two phase morphology which results from microphase separation of "soft" and "hard" segments.

At page 9, lines 3-20, of the present application the terms "soft" and "hard" in the context of segmented polymers are clearly defined relative to their crystalline and/or amorphous nature as follows:

As used herein, a "hard" segment is one that is either crystalline at use temperature or amorphous with a glass transition temperature above use temperature (i.e., glassy), and a "soft" segment is one that is amorphous with a glass transition temperature below use temperature (i.e., rubbery). A crystalline or glassy moiety or hard segment is one that adds considerable strength and higher modulus to the polymer. Similarly, a rubbery moiety or soft segment is one that adds flexibility and lower modulus, but may add strength particularly if it undergoes strain crystallization, for example. ...

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As used herein, a "crystalline" material or segment is one that has ordered domains. A "noncrystalline" material or segment is one that is amorphous (a noncrystalline material may be glassy or rubbery). A "strain crystallizing" material is one that forms ordered domains when a strain or mechanical force is applied.

In light of these definitions, it is respectfully submitted that the term "soft" is sufficiently defined. Furthermore, it would be a simple matter for the skilled artisan to determine whether or not any given polymer material included at least one soft segment comprising a group of this formula.

Gunatillake327 is directed to a non-elastomeric polyurethane and Gunatillake863 is directed to an elastomeric polyurethane, wherein the chain extenders are derived from silicon-containing diols. These polyurethane compositions comprise a chain extender including a silicon-containing diol. One of skill in the art in polyurethane chemistry would understand that a "chain extender" forms a hard segment. Applicants explain at page 7, line 32 through page 8, line 13 of their specification that the chain extenders of Gunatillake863 (which are analogous to the chain extenders of Gunatillake327) form hard segments.

It is respectfully submitted that the Examiner has not provided sufficient evidence to doubt Applicants' assertion that these documents disclose hard segments, not soft segments, which are clearly distinguishable terms, as defined in Applicants' specification. Applicants request withdrawal of these rejections.

**The 35 U.S.C. §103 Rejection**

The Examiner rejected claims 1-11, 14-15 and 17 under 35 U.S.C. §103(a) as being unpatentable over Zdrahala (U.S. 4,647,643). This rejection is respectfully traversed.

Although the generic structure (Formula I) in Zdrahala refers to the W groups as "divalent linking groups," and discloses alkylene bridges of from 1 to 4 carbon atoms, all the examples are directed to siloxanes. There is no disclosure of segmented polymers wherein each R<sup>3</sup> is independently an unsubstituted straight chain alkylene group that contains more than 4

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carbons, as recited in Applicants' claims.

Furthermore, there is no reason to modify the teaching of Zdrahala to obtain Applicants' invention. There are significant physical advantages to the segmented polymers wherein each  $R^3$  is independently an unsubstituted straight chain alkylene group that contains more than 4 carbons, as recited in Applicants' claims. Applicants submit several documents that are directed to polyurethanes and describe the relationship between chain length and strain crystallization. These evidence the position that the Zdrahala polymers (with alkylene bridges of from 1 to 4 carbon atoms) will generally not strain crystallize and will have inferior mechanical properties compared to Applicants' polymers.

For example, the Wilkes document (*J. Macromol. Sci.-Phys.*, 1973; B7(1):157-175) discusses stress-crystallization, which is the same as strain-crystallization, in segmented polyurethanes. At page 160 the importance of stress-crystallization in achieving high tensile strength is discussed. It states that hydrocarbon polymers such as polyethylene and propylene can undergo this type of crystallization. This document shows thermal and x-ray evidence of stress-crystallization in polyether (tetramethyl ether, C4) and polyester (tetramethyl adipate, C4) soft segments.

The Bonart document (*J. Macromol. Sci.-Phys.*, 1968 March, B2(1):115-138) demonstrates elongation-crystallization, which is also the same as strain-crystallization, with poly(tetramethyl ether)urethane starting at about 150% elongation.

The Hardman and Torkelson document (*Encyclopedia of Polymer Science and Engineering*, Vol. 15, Second Edition, 1989) at page 246 states that silicone resins and unreinforced elastomers do not crystallize under ordinary conditions and therefore have poor mechanical properties, even at high molecular weights. Page 272 discusses this point further. The reason silicone rubbers do not strain crystallize is that the dimethyl substitution on the silicon atoms prevents tight chain packing necessary for strain crystallization to occur.

The Ward document (<http://www.devicelink.com/mddi/archive/00/04/011.html>, <http://www.devicelink.com/mddi/archive/00/04/table2.html>) describes attempts to make copolymers of silicone and polyurethane to combine the desirable silicone biostability and

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polyurethane mechanical properties. Ward states that increasing the amount of silicone in these copolymers results in more silicone-like properties. The table demonstrates this, showing a silicone urethane copolymer, denoted MDI-BD-PSX, which has mechanical properties only slightly improved over typical silicone elastomers.

Applicants' claimed invention involves increasing the spacing between dimethyl silane groups by increasing the hydrocarbon chain length, with the intent of allowing strain crystallization to occur and improving the mechanical properties of the resulting polymer. It is respectfully submitted that at least four carbons between dimethyl silane groups provide strain crystallization. The DiDomenico and Tapsak patents suggest that 6 or more is optimal.

The polyolefin industry generally accepts (see, e.g., the Dorset document, *J. Phys. Chem.*, 1991; 95:938-940) that 22 carbons between branch points are required to observe spontaneous crystallization in polyethylene, but this crystallization does not require strain. For preferred embodiments (e.g., claim 9) in which spontaneous crystallization of the soft segment is undesirable, the desired spacing between dimethyl silane groups is no greater than 20 carbons to allow strain crystallization, but avoid spontaneous crystallization.

Since the relevant disclosure cited by the Examiner in Zdrahada limit spacing to no more than 4 carbons, it is respectfully submitted that the resultant polymers will not strain crystallize and will have inferior mechanical properties compared to Applicants' polymers.

Withdrawal of this rejection is respectfully requested.

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**For: POLYMERS WITH SOFT SEGMENTS CONTAINING SILANE-CONTAINING GROUPS, MEDICAL DEVICES, AND METHODS****Summary**

It is respectfully submitted that the pending claims 1-11, 13-28, 30-34, 39-40 are in condition for allowance and notification to that effect is respectfully requested. The Examiner is invited to contact Applicants' Representatives, at the below-listed telephone number, if it is believed that prosecution of this application may be assisted thereby.

Respectfully submitted

By

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**CERTIFICATE UNDER 37 CFR §1.8:**

The undersigned hereby certifies that the Transmittal Letter and the paper(s), as described hereinabove, are being transmitted by facsimile in accordance with 37 CFR §1.6(d) to the Patent and Trademark Office, addressed to Mail Stop Amendment, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on this 22nd day of December, 2006, at 10pm (EST).

By:

Name:

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